

FORM PTO-1390  
(REV 10-2000)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371

4002-2734

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

09/869813

INTERNATIONAL APPLICATION NO.  
PCT/US00/00604INTERNATIONAL FILING DATE  
11 January 2000PRIORITY DATE CLAIMED  
11 January 1999TITLE OF INVENTION  
INTERVERTEBRAL SPACERS WITH SIDE WALL ACCESSIBLE INTERIOR CAVITY

APPLICANT(S) FOR DO/EO/US

Lawrence M. BOYD; J. Kenneth BURKUS; John D. DORCHAK; Bradley T. ESTES, Eddie F. RAY, III

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to promptly begin national examination procedures (35 U.S.C. 371(f)).
4. ☐ The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(3)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19(35 U.S.C. 371(c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☒ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). (unsigned)
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

## Items 11 to 16 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A **FIRST** preliminary amendment.
- ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:
  - a. PCT Request
  - b. International Publication
  - c. Notification of Receipt of Demand
  - d. Notification of Transmittal of the International Search Report
  - e. Response to International Search Report
  - f. FORM PCT/IB/304; 332
  - g. Response to Written Opinion
  - h. Notice of the Recording of a Change
  - i. International Preliminary Examination Report
  - j. Return Postcard

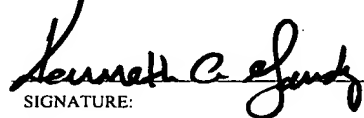
Express Mail Label No.: EL414479826US

Date of Deposit: 5 July 2001

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Susan K. Geller

Signature of person mailing paper or fee

U.S. APPLICATION NO. (if known, see 37 CFR 1.49)		INTERNATIONAL APPLICATION NO. PCT/US00/00604		ATTORNEY'S DOCKET NUMBER 4002-2734	
17. <input checked="" type="checkbox"/> The following fees are submitted: <b>BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5)):</b> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO ..... \$1000.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO ..... \$860.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... \$710.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... \$690.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) ..... \$100.00 <b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b>				CALCULATIONS PTO USE ONLY	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$ 690 --	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$ 130 --	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	52 - 20 =	32	X \$18.00	\$ 576 --	
Independent claims	8 - 3 =	5	X \$80.00	\$ 400 --	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$270.00	\$ N/A	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$ 1,796 --	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$ N/A	
<b>SUBTOTAL =</b>				\$ 1,796 --	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$ N/A	
<b>TOTAL NATIONAL FEE =</b>				\$ 1,796 --	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$ N/A	
<b>TOTAL FEES ENCLOSED =</b>				\$ 1,796 --	
				Amount to be refunded:	\$
				charged:	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>1,796.00</u> to cover the above fees is enclosed.					
b. <input type="checkbox"/> Please charge my Deposit Account No. <u>23-3030</u> in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.					
c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>23-3030</u> . A duplicate copy of this sheet is enclosed.					
<b>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</b>					
SEND ALL CORRESPONDENCE TO:					
Kenneth A. GANDY WOODARD, EMHARDT, NAUGHTON, MORIARTY & MCNETT Bank One Center/Tower, Suite 3700 111 Monument Circle Indianapolis, Indiana 46204 US			<div style="text-align: center;">             SIGNATURE: Kenneth A. Gandy            NAME: Kenneth A. Gandy            #33,386            REGISTRATION NUMBER         </div>		

IN THE INTERNATIONAL BUREAU OF WIPO

In re PCT application of	) Authorized Officer:
SDGI HOLDINGS, INC., et al	) Nathalie Geisler
	)
International Application	)
Number PCT/US00/00604	) Mailing Date
	) 28 November 2000
International Filing Date	)
11 January 2000	) Agent's File
	) Reference:
Title of Invention	) 9904PC1/2280
INTERVERTEBRAL SPACERS WITH	)
SIDE WALL ACCESSIBLE INTERIOR	)
CAVITY	)

**RESPONSE TO THE INTERNATIONAL SEARCH REPORT**

The International Bureau  
WIPO  
34, chemin des Colombettes  
1211 Geneva 20  
Switzerland

Dear Sir/Madam:

In response to the International Search Report mailed 03 October 2000, regarding the above-referenced PCT patent Application, applicant does not wish to make any amendments at this time.

Respectfully submitted

By 

Kenneth A. Gandy, #33,386  
Woodard, Emhardt, Naughton,  
Moriarty & McNett  
Bank One Center/Tower, Suite 3700  
111 Monument Circle  
Indianapolis, Indiana 46204 US  
(317) 634-3456

In re PCT application of	) Authorized Officer:
SDGI HOLDINGS, INC., et al	) B. Hedels
	)
International Application	)
Number PCT/US00/00604	) Mailing Date
	) 5 February 2001
International Filing Date	)
11 January 2000	) Agent's File
	) Reference:
Title of Invention	) 9904PC1/2280
INTERVERTEBRAL SPACERS WITH	)
SIDE WALL ACCESSIBLE INTERIOR	)
CAVITY	)

**RESPONSE TO WRITTEN OPINION OF THE INTERNATIONAL  
PRELIMINARY EXAMINING AUTHORITY**

The International Preliminary Examining Authority  
European Patent Office  
Erhardstrasse 27  
D-80298 Munich  
Germany

Dear Sir/Madam:

In response to the Written Opinion from the International Preliminary Examining Authority mailed 06 November 2000, please consider the following. Substitute sheet 29 is included herein as claim 52 has been amended. The remaining claims remain unchanged.

**REMARKS**

Claims 1-57 are pending in the above-referenced international application. A negative indication with respect to novelty has given with respect to claims 1, 19, 20, 34, 52, 53. Moreover, the Opinion asserts that the methods defined in claims 40-51 relate to methods for treatment of the human or animal body by surgery or therapy and no examination has been

performed with respect to these claims. In light of the discussion below, it is believed that all prior art rejections have been overcome.

It is asserted in the Opinion that the features of claims 1, 19, 20, 34, 52, 53 are anticipated by the device and system in U.S. Patent no. 5,593,409 (D1) and particularly points out FIG. 43 in reference D1 showing implants 900a and 900b. However, reference D1 does not teach or suggest each and every element in the objected to claims.

For example, the spacers defined by claims 1, 19, 20, 34, and 53 have side openings and preferably features that allow them to nest within each other. Such spacers are advantageous as they allow, for example, close placement of the spacers in the intervertebral disc space. Moreover, the side openings may provide access to the interior cavity of the spacers either before or after implantation so that osteogenic material can be placed in the cavity of the spacers. The side openings can further facilitate insertion of the spacers in the intervertebral disc space.

Conversely, reference D1 does not teach or suggest a spacer having such side wall openings as can be seen by referring to FIG. 43 and column 15, lines 25-49 of the reference. No such spacers are seen in this or any other figure, or described anywhere in the text of the patent. Moreover, the spacers of FIG. 43 in reference D1 do not include an interior cavity along with side wall openings as recited in the objected to claims.

Moreover, claim 52 has been amended to recite that the side walls define an opening that is configured for passage of osteogenic material into the cavity. No such opening in a side wall of a spacer wherein the side wall and end walls have an external profile defining an arc of a circle as recited in claim 52 is taught or suggested in reference D1.

In reference to the objections delineated in VIII-1, 3, 5, and 7-9, applicant chooses not to make any changes to the claims as the requirements of the various countries the application will be nationalized in may vary.

In view of the foregoing, applicant respectfully requests reconsideration and withdrawal of the objections in the Written Opinion relating to novelty. Establishment of an International Preliminary Examination Report that is positive in all respects as to claims 1-39 and 52-57 is respectfully requested.

Respectfully submitted

By 

Jason J. Schwartz, #43,910  
Woodard, Emhardt, Naughton,  
Moriarty & McNett  
Bank One Center/Tower, Suite 3700  
111 Monument Circle  
Indianapolis, Indiana 46204 US  
(317) 634-3456

DNK-1999-004-PA-PCT1:JJS:116263

(b) preparing said adjacent vertebra to receive the elongated body in an intervertebral space between adjacent vertebrae; and

(c) placing the first elongated body into the intervertebral space.

5           47. The method of claim 46, further comprising packing osteogenic material into said interior cavity of said first spacer prior to the placing step.

          48. The method of claim 46, further comprising implanting a second spacer into the intervertebral space after the placing step.

10           49. The method of claim 48, further comprising orienting said second spacer so that it nests within said first spacer.

          50. The method of claim 49, wherein said first and second interbody fusion spacers are comprised of metal.

15           51. The method of claim 50, wherein said first elongated body has a first plurality of openings for bone ingrowth extending from said first outer surface into said interior cavity.

          52. An interbody fusion spacer, comprising:  
an elongate body having end walls and a side wall extending between said end walls, said side wall and said end walls defining an interior cavity, said side walls further defining an opening configured for passage of  
20 osteogenic material into said cavity;

said end walls each having an external profile comprising a first portion defining an arc of a circle, said arc extending from 180° to 324° around the circle; said external profile also comprising a second portion defining a concave surface;